

SUPPORT FOR THE AMENDMENTS

Claims 5 and 10-15 have been amended.

Support for the amendment of Claims 5 and 10-15 is provided at paragraphs [0009], [0010], [0014], [0018], and the Examples

No new matter has been added by the present amendment.

REMARKS

Claims 1-5 and 7-15 are pending in the present application.

At the outset, Applicants wish to thank Examiner Sznaidman for the helpful and courteous discussion with their undersigned Representative on November 9, 2010. During this discussion various amendments and arguments in traverse of the outstanding rejections were discussed. The content of this discussion is reflected in the following comments. Reconsideration of the outstanding rejections is requested.

The rejections of (a) Claims 5, 10, and 14 under 35 U.S.C. §103(a) over Iwao et al (JP 2003-095942) and (b) Claims 11-13 and 15 under 35 U.S.C. §103(a) over Iwao et al (JP 2003-095942) in view of Demeule et al (Curr. Medic. Chem. 2002) is respectfully traversed.

In the outstanding Office Action, the Examiner has reinstated Iwao et al (JP 2003-095942) in making a new ground of rejection. In the response filed June 8, 2009 and November 4, 2008, Applicants argued Iwao et al is silent with respect to improving endurance in a subject in need thereof, where the subject in need thereof is a subject who needs to do exercise requiring endurance or labor requiring repeated muscle exercise. Citing *Jansen v. Rexall Sundown Inc.*, 342 F.3d 1329, 1332, 68 USPQ2d 1154, 1158 (Fed. Cir. 2003) Applicants note that as a result of this failure by Iwao et al, the claimed invention is not anticipated by Iwao et al.

Specifically, although Iwao et al disclose activation of GLUT4 translocation and glucose intake activation results in an increased ability for exercise, the word “ability for exercise” has several meanings which are not synonymous with or the same as improved endurance. The “ability for exercise” relates to, for example, agility, muscle force,

instantaneous force. As evidenced by the references cited with the response filed on November 4, 2008, (Gaster et al, Shichun et al, and Tsao et al), activation of GLUT4 translocation and glucose intake activation do not have any relation with endurance improving effect. Indeed, activation of GLUT4 translocation has negative effects on endurance (lactate level and metabolize carbohydrate) as illustrated by the combined disclosures of the aforementioned previously submitted references.

Moreover, Applicants respectfully submit that there is no disclosure or suggestion in Iwao et al to administer to a subject who needs to do exercise requiring endurance or labor requiring repeated muscle exercise an effective dose of a composition comprising catechins as claimed in Claim 5. As such, Applicants submit that the claimed invention is not obvious in view Iwao et al.

Although the Examiner agrees that the failure of Iwao et al to disclose the specific subjects to be treated, the Examiner's position is that this is only sufficient to overcome the anticipation rejection. The Examiner, however, holds that the the claimed invention is obvious in view of Iwao et al. Specifically, the Examiner states that Iwao et al disclose "a method to reinforce and increase activation of the muscular system, improvement in athletic ability (improving endurance), fatigue mitigation (ameliorating fatigue) by administering [a catechin] (see paragraphs [0011]-[0013])." Citing paragraph [0018], the Examiner indicates that by "catechin" Iwao et al encompass at least epicatechingallate, epigallocatechingallate, and catechingallate.

In view of this disclosure, the Examiner has taken the position that it would have been obvious to "administer catechins to any person in need of such improvements [reinforce and increase activation of the muscular system, improvement in athletic ability (improving endurance), fatigue mitigation (ameliorating fatigue)], like for example subject that regularly

exercise, are involved in sports or any other activity, including walking, that requires repeated muscle exercise, thus resulting in the practice of claims 5, 10, and 14 with a reasonable expectation of success.”

Solely to expedite examination of the claimed invention, Applicants have amended the claimed method to be drawn to a “method for improving endurance, which comprises administering to a subject in need thereof an effective dose of a composition comprising at least one catechin, wherein said subject in need thereof is a subject who needs to do exercise requiring endurance or labor requiring repeated muscle exercise, wherein said catechin is at least one catechin selected from the group consisting of gallocatechin and epigallocatechin.” That is the claimed method requires the administration of at least gallocatechin and/or epigallocatechin (i.e., the catechins recited in previously pending Claims 11, 12, and 15) to a subject in need of improving endurance where the subject needs to do exercise requiring endurance or labor requiring repeated muscle exercise. Applicants submit that the claimed method is not obvious in view of Iwao et al, even when viewed with Demeule et al.

The Examiner states that gallocatechin and/or epigallocatechin are not disclosed by Iwao et al, but the Examiner cites Demeule et al in addition to Iwao et al to support the position that it would generally be obvious to replace epicatechingallate, epigallocatechingallate, and catechingallate with gallocatechin and/or epigallocatechin with a reasonable expectation of success in their interchangeability. The basis for this position is that Demeule et al show significant structural similarity between catechins, as well as similarities in their biological activities. Accordingly, the Examiner’s position is that the skilled artisan would expect that gallocatechin and/or epigallocatechin would also bring about the claimed result. Applicants disagree with this position for at least the following reasons.

As evidenced by the full English translation of Iwao et al **submitted herewith**, Iwao et al do disclose gallocatechin and/or epigallocatechin. Specifically, at paragraphs [0029], paragraph [0044], and Figure 8 recite these specific catechins designated as (GC) and (EGC), respectively. However, contrary to the Examiner's allegations based on Iwao et al and Demeule et al that administration of gallocatechin and/or epigallocatechin would provide the claimed effect, paragraphs [0044], [0045], and Figure 8 of Iwao et al clearly show that catechins which have gallate ester show the inhibition of glucose uptake in fat cells, but catechins which do not have the gallate ester (e.g., gallocatechin and/or epigallocatechin) do not show the inhibition of glucose uptake in fat cells.

Figure 8 of Iwao et al, which as summarized in paragraph [0044], clearly shows a structure-specific property of catechins which have gallate ester, where the gallocatechin and epigallocatechin did not decrease the amount of glucose uptake relative to the control or the gallate esters. Accordingly, based on paragraphs [0044], [0045], and Figure 8 of Iwao et al, the skilled artisan would not expect catechins, which do not have gallate ester, to show endurance improvement effect as presently claimed. .

Accordingly, Applicants submit that Iwao et al, even when viewed with Demeule et al, is insufficient to support even a prima facie case of obviousness and there would be no reasonable expectation of success based on these disclosures.

Withdrawal of this ground of rejection is requested.

Finally, the Office has issued three sets of provisional obviousness-type double patenting rejections based on the following three U.S. Applications: 12/307,342; 11/626,032; and 11/045,312. Applicants make no statement with respect to the propriety of these rejections. Nonetheless, noting that it is not clear what scope of allowable subject matter

exists in the present application or in the co-pending cited applications, Applicants request that these provisional obviousness-type double patenting rejections be held in abeyance. If it is determined that a Terminal Disclaimer is necessary, Applicants will consider filing the same at a later date.

The Examiner is reminded that MPEP §804 indicates that: "If "provisional" ODP rejections in two applications are the only rejections remaining in those applications, the examiner should withdraw the ODP rejection in the earlier filed application thereby permitting that application to issue without need of a terminal disclaimer."

Applicants submit that the present application is now in condition for allowance. Early notification of such action is earnestly solicited.

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